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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,609	04/05/2001	Bruce L. Roberts	GA0150C	4367

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GENZYME CORPORATION
LEGAL DEPARTMENT
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FRAMINGHAM, MA 01701-9322

EXAMINER

RISHI, ANJUM I

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,609

Applicant(s)

ROBERTS ET AL.

Examiner

Anjum I Rishi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 7-9, and 12, drawn to a method to identify cancer therapeutic by identifying a protein which is expressed in the target cancer cell and determining if the protein is immunogenic and to design a cancer vaccine using the protein, classified in class 514, subclass 02
- II. Claims 1, 3, 8, and 10-16, drawn to a method to identify cancer therapeutic by identifying a polynucleotide which is expressed in the target cancer cell and delivering the peptide encoded by the polynucleotide to a subject and further administering cytokine and/or co-stimulatory molecule to induce an immune response against a target cell, classified in class 514, subclass 44.
- III. Claims 1, 4, and 17-20, drawn to a method to identify cancer therapeutic by administering to the subject immune effector cells reactive with immunogenic protein, classified in class 424, subclass 93.21
- IV. Claims 1, 5-6, 21-24, drawn to a method to identify cancer therapeutics by administering monoclonal antibodies reactive with immunogenic protein, classified in class 530, subclass 388.1.

Claim 1 is a linking claim generic to all groups. Claims 8 and 12 are linking for groups I and II.

The inventions are distinct, each from the other because of the following reasons: Inventions I and II are distinct, each from the other in that peptides and nucleic acids are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for substantially different purposes. It is particularly noted that the nucleic acid is not required for the production of the peptide as peptides can be chemically synthesized or purified from cells. Further, while the method to identify nucleotides is shared, the inventions are distinct in testing of the immunogen and administering a co-stimulatory molecule.

Inventions I and III are distinct, each from the other in that peptides and cells are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for substantially different purposes. Further, while the method to identify nucleotides is shared, the inventions are distinct in administration of immune effector cells. Additionally, Invention I is not required for invention II, and vice versa.

Inventions I and IV are distinct, each from the other in that peptides and antibodies are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for substantially different purposes. Further, while the method to identify nucleotides is shared, the inventions are distinct in administering an antibody. Additionally, Invention I is not required for invention IV, and vice versa.

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Inventions II and III are distinct, each from the other in that nucleic acids and immune effector cells are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for different purposes. Further, while the method to identify nucleotides is shared, the inventions are distinct in administering immune effector cells. Additionally, Invention I. Additionally, invention II is not required to implement invention III and vice versa.

Inventions II and IV are distinct, each from the other in that nucleic acids and antibodies are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for different purposes. Further, while the method to identify nucleotides is shared, the inventions are distinct in administering an antibody. Additionally, invention II is not required to implement invention IV and vice versa.

Inventions III and IV are distinct, each from the other in that immune effector cells and antibodies are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for different purposes. Further, while the method to identify nucleotides is shared, the inventions are distinct in administering an antibody. Additionally, invention II is not invention III is not required to implement invention IV and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

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matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication should be directed to Anjum I Rishi at telephone number (703)308-4422. Fax number (703) 308-4242. The examiner can normally be reached on Mon-Fri (9:00 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor, Karen Hauda can be reached at (703) 305-6608. The fax number for this organization is (703) 308-4242.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the art unit patent analyst, Kay Pinkney whose telephone number is (703) 305-3553.

A.Rishi


A.M.S. BECKERLEG
PATENT EXAMINER